

## Complete Summary

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### **GUIDELINE TITLE**

Acute medical and surgical management. In: Clinical guidelines for acute stroke management.

### **BIBLIOGRAPHIC SOURCE(S)**

Acute medical and surgical management. In: National Stroke Foundation. Clinical guidelines for acute stroke management. Melbourne (Australia): National Stroke Foundation; 2007 Oct. p. 22-9.

### **GUIDELINE STATUS**

This is the current release of the guideline.

## **COMPLETE SUMMARY CONTENT**

SCOPE  
METHODOLOGY - including Rating Scheme and Cost Analysis  
RECOMMENDATIONS  
EVIDENCE SUPPORTING THE RECOMMENDATIONS  
BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS  
CONTRAINDICATIONS  
QUALIFYING STATEMENTS  
IMPLEMENTATION OF THE GUIDELINE  
INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT  
CATEGORIES  
IDENTIFYING INFORMATION AND AVAILABILITY  
DISCLAIMER

## **SCOPE**

### **DISEASE/CONDITION(S)**

- Acute stroke (ischemia or intracerebral hemorrhage)
- Transient ischemic attack (TIA)

### **GUIDELINE CATEGORY**

Evaluation  
Management  
Prevention  
Treatment

### **CLINICAL SPECIALTY**

Critical Care  
Emergency Medicine  
Geriatrics  
Neurology  
Nursing  
Pharmacology  
Preventive Medicine

## **INTENDED USERS**

Advanced Practice Nurses  
Health Plans  
Hospitals  
Nurses  
Patients  
Pharmacists  
Physician Assistants  
Physicians

## **GUIDELINE OBJECTIVE(S)**

- To provide evidence-based recommendations related to acute stroke care
- To help health care workers improve the quality and effectiveness of the care they provide
- To provide a logical framework from pre-hospital care through to discharge and follow up in the community

## **TARGET POPULATION**

Adults with suspected or known acute stroke or transient ischemic attack (TIA) in the early phase of care

**Note:** "Early" is defined as the first seven days of care. This guideline does NOT include recommendations on the care of those with subarachnoid hemorrhage or the care of children.

## **INTERVENTIONS AND PRACTICES CONSIDERED**

### **Medical Management**

1. Intravenous recombinant tissue plasminogen activator (rt-PA) in selected patients
2. Use of specialized, interdisciplinary care
3. Use of a patient register for monitoring and review
4. Other antithrombotic therapy: e.g., aspirin
5. Anticoagulation in carefully selected patients
6. Antihypertensive therapy
7. Recombinant activated factor VII (rFVIIa) for intracerebral haemorrhage (ICH)(not recommended outside clinical trials)
8. General acute stroke care
  - Physiological monitoring (including Glasgow Coma Scale)
  - Oxygen therapy
  - Glycemic control

- Neuroprotective agents (not recommended outside clinical trials)
- Complementary and alternative therapies (not recommended)

### **Surgical Management**

1. Hemicraniectomy for significant middle cerebral artery infarction
2. Intracranial endovascular surgery (not recommended)
3. Stereotactic surgery for ICH in limited circumstances
4. Craniotomy for ICH with superficial hematoma
5. Surgical evacuation of cerebellar hemisphere hematoma associated with ICH

### **MAJOR OUTCOMES CONSIDERED**

- Changes in hemodynamics, blood pressure, and blood sugar
- Mortality and morbidity
- 30-Day and 90-day survival rates
- Rate of treatment-related hemorrhage
- Rate of perioperative stroke
- Functional outcome (e.g., Barthel Index and Rankin Scale scores)
- Length of hospitalization
- Cost of care

## **METHODOLOGY**

### **METHODS USED TO COLLECT/SELECT EVIDENCE**

Hand-searches of Published Literature (Primary Sources)  
 Hand-searches of Published Literature (Secondary Sources)  
 Searches of Electronic Databases

### **DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE**

#### **Systematic Searches and Literature Review**

The systematic identification of relevant literature was conducted according to National Health and Medical Research Council (NHMRC) standards between July and November 2006. Previous international and national stroke guidelines were identified and evaluated using the AGREE tool. Guidelines developed by the Royal College of Physicians in the United Kingdom (UK) in 2004 were deemed the most recent and robust guidelines and hence were used as a basis for updating the literature searches. An external consultant was used to undertake all the electronic database searches.

#### **Question Formulation**

89 clinical questions were developed by the Expert Working Group (EWG) to address interventions relevant to acute stroke care. The questions generally queried the effects of a specific intervention and were developed in three parts: the intervention, the population and the outcomes. An example is "What is the effect of anticonvulsant therapy on reducing seizures in people with post-stroke seizures?" In this example, anticonvulsant therapy is the intervention, reduction

of post-stroke seizures is the outcome, and the population is people with post-stroke seizures.

### **Finding Relevant Studies**

For this guideline searching, there could be no single search coverage for all 89 questions: some sections of the guidelines need updating only from 2003, some are topics not previously addressed in the guidelines, some have already been well researched by other reputable guidelines authorities while some have no comprehensive meta-analysis relating to them.

In order to have some structure to the searching and to make filtering of the references more manageable, the questions were searched and stored in separate Endnote libraries by broad topics:

1. Organisation of care
2. Discharge planning, transfer of care and integrated community care
3. Pre hospital care
4. Early diagnostic assessment
5. Management in the emergency phase
6. Assessment and management of consequences of stroke
7. Prevention and management of complications
8. Early secondary prevention
9. Palliation and death
10. Transient ischemic attack (TIA)

Each reference within the library was then marked with the questions for which it was relevant. For Australasian Medical Index, EMBASE, Medline and Medline in-process & other non-indexed citations searching was conducted in four broad steps:

- a. Terms for the patient group (P) were abridged from the Cochrane Collaboration's Stroke Group.
- b. Where appropriate, intervention or other factor terms were added.
- c. Relevant evidence filters (Cochrane sensitive filter or Medline diagnostic filter) were applied to the basic search strategies.
- d. If the search was for an update only to National Stroke Foundation (NSF) or other authoritative meta-analysis, the references were limited to years 2003 onwards.

For brevity, search strategies are not included in the original guideline document but are available from the NSF. Table 3 in Appendix A of the original guideline document outlines the number of articles found for each 10 topic areas listed above.

A systematic process for choosing relevant articles occurred. At first, relevant systematic reviews were initially identified. Where no systematic review was found, primary studies were then searched. This initial process was conducted by one member of the working group. Final decision to include and review articles was made by two members of the working group after abstracts were scrutinised. Reference lists of identified articles and other guidelines were then used to identify further trials. The table of contents of a number of key journals for the

last 6 months was also conducted. The following journals were chosen: Stroke, Cerebrovascular Disease, Lancet (and Lancet Neurology), and Archives of Physical Medicine and Rehabilitation. For a number of topics a general internet search was then undertaken (using the "Google" search engine). Finally, where possible, experts in the field were contacted to review the identified studies and suggest other new studies not identified. Hand searching continued until May 2007 and significant studies were included.

## **Cost Analysis**

The Guidelines project officer conducted a separate systematic review for this section. The economic literature was searched with a total of 1484 references retrieved after deduplication (see Table 4 in Appendix A of the original guideline document). One person sorted these and selected 70 potentially relevant articles. These abstracts were scrutinised for omissions by two people and appropriate papers were retrieved and reviewed (n=30).

## **NUMBER OF SOURCE DOCUMENTS**

A total of 30,140 potential articles resulted from the clinical searching. After reviewing abstracts and titles, 1,411 of these were identified as being potentially useful and worth reading in more detail. Only 468 of the original were used to write the Guidelines report and only a final 153 of the 30,140 original references were used to support the Guideline recommendations.

## **METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE**

Expert Consensus

Weighting According to a Rating Scheme (Scheme Given)

## **RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE**

### **Designation of Levels of Evidence According to Type of Research Question**

<b>Level</b>	<b>Intervention</b>	<b>Diagnosis</b>	<b>Prognosis</b>	<b>Aetiology</b>	<b>Screening</b>
I	A systematic review of Level II studies	A systematic review of Level II studies	A systematic review of Level II studies	A systematic review of Level II studies	A systematic review of Level II studies
II	A randomised controlled trial	A study of test accuracy with: an independent, blinded comparison with a valid reference standard,	A prospective cohort study	A prospective cohort study	A randomised controlled trial

Level	Intervention	Diagnosis	Prognosis	Aetiology	Screening
		among consecutive patients with a defined clinical presentation			
III-1	A pseudo-randomised controlled trial (i.e., alternate allocation or some other method)	A study of test accuracy with: an independent, blinded comparison with a valid reference standard, among consecutive patients with a defined clinical presentation	All or none	All or none	A pseudo-randomised controlled trial (i.e., alternate allocation or some other method)
III-2	A comparative study with concurrent controls: <ul style="list-style-type: none"> <li>• Non-randomised experimental trial</li> <li>• Cohort study</li> <li>• Case-control study</li> <li>• Interrupted time series without a parallel control group</li> </ul>	A comparison with a reference standard that does not meet the criteria required for Level II and Level III-1 evidence	Analysis of prognostic factors amongst untreated control patients in a randomised controlled trial	A retrospective cohort study	A comparative study with concurrent controls: <ul style="list-style-type: none"> <li>• Nonrandomised, experimental trial</li> <li>• Cohort study</li> <li>• Case-control study</li> </ul>
III-3	A comparative study without concurrent controls: <ul style="list-style-type: none"> <li>• Historical control study</li> <li>• Two or more single arm study</li> </ul>	Diagnostic case-control study	A retrospective cohort study	A case-control study	A comparative study without concurrent controls: <ul style="list-style-type: none"> <li>• Historical control study</li> <li>• Two or more single arm study</li> </ul>

Level	Intervention	Diagnosis	Prognosis	Aetiology	Screening
	<ul style="list-style-type: none"> <li>Interrupted time series without a parallel control group</li> </ul>				
IV	Case series with either post-test or pre-test/post-test outcomes	Study of diagnostic yield (no reference standard)	Case series or cohort study of patients at different stages of disease	A cross-sectional study	Case series

## METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses  
Systematic Review with Evidence Tables

## DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

### Appraising and Selecting Studies

A standardised appraisal process was used based on that outlined by the Scottish Intercollegiate Guidelines Network (SIGN). Where available, appraisals already undertaken by the Stroke Therapy Evaluation Program (STEP) team were used to avoid duplication. The standardised appraisal form assesses the level of evidence (design and issues of quality), size of effect, relevance, applicability (benefits/harms) and generalisability of studies. Examples of completed checklists can be found on the STEP website ([www.effectivestrokecare.org](http://www.effectivestrokecare.org)). Where Level I or II evidence was unavailable the search was broadened to include lower levels of evidence. Evidence for diagnostic and prognostic studies was also appraised using the SIGN methodology.

### Summarising and Synthesising the Evidence

Details of relevant studies were summarised in evidence tables which form a supplement to this document. The supplement is available for download from the National Stroke Foundation (NSF) website ([www.strokefoundation.com.au](http://www.strokefoundation.com.au)).

For each question the evidence was collated using the draft National Health and Medical Research Council (NHMRC) "Assessing the body of evidence form". The recommended grading matrix was used to guide the strength or grading of the recommendation. For each question, the working group discussed and agreed on draft recommendations. The body of evidence matrix along with the draft recommendation gradings are shown in the original guideline document.

## METHODS USED TO FORMULATE THE RECOMMENDATIONS

## DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The Clinical Guidelines for Acute Stroke Management have been developed according to processes prescribed by the National Health and Medical Research Council (NHMRC) under the direction of an interdisciplinary Expert Working Group (EWG) (see Appendix A in the original guideline document). The draft 'Additional levels of evidence and grades for recommendations for developers of guidelines pilot program 2005-2007' has been used to assist in grading the recommendations along with specifying levels of evidence. Consultation from other individuals and organisations was also included in the development process in line with NHMRC standards. Details about the development methodology and consultation process are outlined in Appendix A in the original guideline document.

A consumer was included in the EWG and has been involved in every phase of the development process, including the development of the clinical questions to guide the literature searching. In addition a number of consumer organisations were specifically sent the draft document and asked to provide any comments reflecting the views of consumers. Finally a two part structured consultation process was also undertaken by an independent team from the University of Queensland on behalf of the National Stroke Foundation to understand the views of consumers on the current document. The first phase discovered the views of consumers on the best process to engage consumers and receive feedback on the guidelines. Based on the results of this qualitative data, consumers from a wide range of locations, stroke severities, carer/survivor mix, and other demographics were collected. For details of the results of this consultation see Appendix A in the original guideline document. In addition, the process of developing the Clinical Guidelines for Acute Stroke Management has importantly included input and advice from stroke survivors and their family/carer.

## RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

### Grading of Recommendations

Grade	Description
<b>A</b>	Body of evidence can be trusted to guide practice
<b>B</b>	Body of evidence can be trusted to guide practice in most situations
<b>C</b>	Body of evidence provides some support for recommendation(s) but care should be taken in its application
<b>D</b>	Body of evidence is weak and recommendation must be applied with caution
<b>Clinical Practice Points</b>	
<b>CPP</b>	Recommended best practice based on clinical experience and expert opinion

## COST ANALYSIS



There is good evidence of cost-effectiveness for the most clinically effective and important stroke prevention and treatment strategies recommended in this guideline. In particular, the findings from a recent modelling exercise in the Australian setting indicate that more widely accessible, evidence-based stroke care could produce substantial economic and health-related benefits and would require only modest investment. The authors suggested that if there was improved access of eligible stroke patients to effective acute care (stroke units and intravenous thrombolysis) and secondary prevention (blood pressure [BP] lowering, warfarin for atrial fibrillation [AF], aspirin in ischaemic stroke and carotid endarterectomy), as well as improved management of BP and AF as primary prevention in the Australian population, then about \$1.06 billion could be recovered as potential cost offsets with recovery of more than 85,000 disability adjusted life years (DALYs). Therefore, clinical guidelines such as these which promote improved treatment and prevention of stroke are an important contribution to achieving such increased access and the cost-effective use of health resources in this country.

See Section 9 titled *Cost and Socioeconomic Implications* in the original guideline document for details of the review of the cost and socioeconomic implications of providing evidence based stroke care supported by the recommendations contained within this guideline.

## **METHOD OF GUIDELINE VALIDATION**

External Peer Review  
Internal Peer Review

## **DESCRIPTION OF METHOD OF GUIDELINE VALIDATION**

Public consultation was undertaken, with the draft document circulated to relevant professional bodies, interested individuals, consumers and consumer organisations over one month from mid April to the third week in May 2007. A public notice was also published in *The Australian* (April 19, 2007). Feedback received during consultation was considered by the Expert Working Group (EWG) and the draft document amended. A formal letter of reply was sent to all individuals and organisations that provided feedback during this period outlining the response taken by the EWG.

In response to the major issues received during consultation an independent expert was asked to review the key studies for the topic in question, in addition to other selected topics, and to advise the working group if the EWG had accurately interpreted and applied the evidence. Independent appraisals of the key studies along with an overall judgement about the appropriateness of the interpretation were provided. Only one recommendation was significantly changed based on this review with the vast majority of recommendations deemed to be in line with the evidence base. Further details are available in Appendix A of the original guideline document.

Several prompted questions were also asked and the response noted in Table 5 in Appendix A of the original guideline document.

## RECOMMENDATIONS

### MAJOR RECOMMENDATIONS

The levels of evidence supporting the recommendations (I-IV) and grades of recommendations (A-D and clinical practice points [CPP]) are defined at the end of the "Major Recommendations" field.

The original guideline document also includes a consumer rating that identifies aspects of care considered to be critical from a patient perspective.

### **Ischaemic Stroke and Transient Ischaemic Attack (TIA)**

#### **Thrombolysis**

Intravenous recombinant tissue plasminogen activator (rt-PA) in acute ischaemic stroke should only be undertaken in patients satisfying specific inclusion and exclusion criteria. (**Grade A; Level I** [(Wardlaw, del Zoppo, & Yamaguchi, 2003; Hacke et al., 2004)])

Intravenous rt-PA in acute ischaemic stroke should be given under the authority of a specialist physician and interdisciplinary acute care team with expert knowledge of stroke management, experience in the use of intravenous thrombolytic therapy and with pathways and protocols available to guide medical, nursing and allied health acute phase management. Pathways or protocols must include guidance in acute blood pressure management. (**Grade C; Level I** [Wardlaw, del Zoppo, & Yamaguchi, 2003] & **Level IV** [Graham, 2003])

Thrombolysis should only be undertaken in a hospital setting with appropriate infrastructure, facilities and networks. (**CPP**)

A minimum set of de-identified data from all patients treated with thrombolysis should be recorded in a central register to allow monitoring, review, comparison and benchmarking of key outcomes measures over time. (**Grade C; Level IV** [(Walhgren et al., 2007)])

#### **Antithrombotic Therapy**

Aspirin (150-300mg) should be given as soon as possible after the onset of stroke symptoms (i.e., within 48 hours) if computed tomography (CT)/magnetic resonance imaging (MRI) scan excludes haemorrhage. (**Grade A; Level I** [(Sandercock et al., 2003)])

The routine use of anticoagulation (e.g., intravenous unfractionated heparin) in unselected patients following ischaemic stroke/TIA is not recommended. (**Grade A; Level I** [(Gubitz, Sandercock, & Counsell, 2004; Paciaroni et al., 2007)])

#### **Blood Pressure Lowering Therapy**

If extremely high blood pressure (e.g., BP >220/120) exists, instituting or increasing antihypertensive therapy may be started, but blood pressure should be cautiously reduced (e.g., by no more than 10-20%) and the patient observed for signs of neurological deterioration. (**CPP**)

Pre-existing antihypertensive therapy may be continued (orally or via nasogastric tube) provided there is no symptomatic hypotension or other reason to withhold treatment. (**CPP**)

### **Surgery for Ischaemic Stroke**

Selected patients (e.g., 18-60 years where surgery can occur within 48 hours of symptom onset) with significant middle cerebral artery infarction should be urgently referred to a neurosurgeon for consideration of hemicraniectomy. (**Grade A; Level I** [Vahedi et al., 2007])

There is currently insufficient evidence to make recommendations about the use of intracranial endovascular surgery. (**Level I** [Cruz-Flores & Diamond, 2006])

### **Intracerebral Haemorrhage (ICH)**

The use of haemostatic drug treatment with recombinant activated factor VII (rFVIIa) is currently considered experimental and is not recommended for use outside a clinical trial. (**Grade B; Level I** [You & Al-Shahi, 2006])

The routine use of surgery is not recommended for patients with supratentorial haematoma but may be considered in certain circumstances, including:

- Stereotactic surgery for patients with deep ICH. (**Grade C; Level I** [Teernstra, Evers, & Kessels, 2006])
- Craniotomy for patients where haematoma is superficial (<1cm from surface). (**Grade C; Level II** [Mendelow et al., 2005])

Surgical evacuation may be undertaken for cerebellar hemisphere haematomas >3cm diameter in selected patients. (**CPP**)

In ICH patients who have a history of hypertension, mean arterial pressure should be maintained below 130 mm Hg. (**CPP**)

### **General Acute Stroke Care**

#### **Physiological Monitoring**

Patients should have their neurological status (including Glasgow Coma Scale) and vital signs including pulse, blood pressure, temperature, oxygen saturation, glucose, and respiratory pattern monitored and documented regularly during the acute phase, the frequency of such observations being determined by the patient's status. (**Grade C, Level II** [Sulter et al., 2003] & **Level III-2** [Silva et al., 2005; Cavallini et al., 2003])

#### **Oxygen Therapy**

Patients who are hypoxic should be given oxygen supplementation. (**CPP**)

### **Glycaemic Control**

Patients with hyperglycaemia should have their blood glucose level monitored and appropriate glycaemic therapy instituted to ensure euglycaemia, especially if the patient is diabetic. Hypoglycaemia should be avoided. (**CPP**)

Intensive, early maintenance of euglycaemia is currently not recommended. (**Grade B; Level II** [Gray et al., 2007])

### **Neuroprotective Agents**

The use of putative neuroprotectors should only be used if part of a randomised controlled trial. (**Grade A; Level I & II** [Ladurner, Kalvach, & Moessler, 2005; Muir et al., 2004; Krams et al., 2003; Muir & Lees, 2003])

### **Complementary and Alternative Therapy**

The routine use of the following complementary and alternative therapies are not recommended:

- Acupuncture (**Grade B, Level I** [Wu et al., 2006; Zhang, et al., 2005])
- Ginkgo biloba extract or Dan shen agents (**Grade B, Level I** [Wu, Liu, & Zhang, 2007; Zeng, et al., 2005])
- Reiki therapy (**Grade C, Level II** [Shiflett et al., 2002])
- Other alternative therapies. (**CPP**)

Health professionals should be aware of different forms of complementary and alternative therapies and be available to discuss these with stroke survivors and their families. (**CPP**)

### **Definitions:**

#### **Levels of Evidence**

<b>Level</b>	<b>Intervention</b>	<b>Diagnosis</b>	<b>Prognosis</b>	<b>Aetiology</b>	<b>Screening</b>
I	A systematic review of Level II studies	A systematic review of Level II studies	A systematic review of Level II studies	A systematic review of Level II studies	A systematic review of Level II studies
II	A randomised controlled trial	A study of test accuracy with: an independent, blinded comparison with a valid	A prospective cohort study	A prospective cohort study	A randomised controlled trial

Level	Intervention	Diagnosis	Prognosis	Aetiology	Screening
		reference standard, among consecutive patients with a defined clinical presentation			
III-1	A pseudo-randomised controlled trial (i.e., alternate allocation or some other method)	A study of test accuracy with: an independent, blinded comparison with a valid reference standard, among consecutive patients with a defined clinical presentation	All or none	All or none	A pseudo-randomised controlled trial (i.e., alternate allocation or some other method)
III-2	A comparative study with concurrent controls: <ul style="list-style-type: none"> <li>• Non-randomised experimental trial</li> <li>• Cohort study</li> <li>• Case-control study</li> <li>• Interrupted time series without a parallel control group</li> </ul>	A comparison with a reference standard that does not meet the criteria required for Level II and Level III-1 evidence	Analysis of prognostic factors amongst untreated control patients in a randomised controlled trial	A retrospective cohort study	A comparative study with concurrent controls: <ul style="list-style-type: none"> <li>• Nonrandomised, experimental trial</li> <li>• Cohort study</li> <li>• Case-control study</li> </ul>
III-3	A comparative study without concurrent controls: <ul style="list-style-type: none"> <li>• Historical control study</li> <li>• Two or more</li> </ul>	Diagnostic case-control study	A retrospective cohort study	A case-control study	A comparative study without concurrent controls: <ul style="list-style-type: none"> <li>• Historical control study</li> <li>• Two or more single</li> </ul>

Level	Intervention	Diagnosis	Prognosis	Aetiology	Screening
	single arm study <ul style="list-style-type: none"> <li>Interrupted time series without a parallel control group</li> </ul>				arm study
IV	Case series with either post-test or pre-test/post-test outcomes	Study of diagnostic yield (no reference standard)	Case series or cohort study of patients at different stages of disease	A cross-sectional study	Case series

### Grading of Recommendations

Grade	Description
<b>A</b>	Body of evidence can be trusted to guide practice
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<b>C</b>	Body of evidence provides some support for recommendation(s) but care should be taken in its application
<b>D</b>	Body of evidence is weak and recommendation must be applied with caution
<b>Clinical Practice Points</b>	
<b>CPP</b>	Recommended best practice based on clinical experience and expert opinion

### CLINICAL ALGORITHM(S)

None provided

## EVIDENCE SUPPORTING THE RECOMMENDATIONS

### REFERENCES SUPPORTING THE RECOMMENDATIONS

[References open in a new window](#)

### TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

## BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

### POTENTIAL BENEFITS

- Prevention of further ischaemic events
- Prevention of costly complications
- Reduced morbidity and mortality

### POTENTIAL HARMS

- Thrombolysis (all agents pooled) shows a net benefit, but is associated with a definite risk of intracerebral haemorrhage and increased mortality at the end of 3 or 6 month follow-up.
- Anticoagulation (e.g., intravenous unfractionated heparin) has a potentially more potent antithrombotic effect and demonstrates greater protection from clots in the leg or lungs; however, the harm of increased bleeding negates any such benefits when compared with aspirin even in patients with cardioembolic stroke.
- Acute blood pressure therapy (i.e., within first 48 hours) remains controversial with both high and low blood pressure found to negatively affect patient outcomes.
- Evidence from case series with three or more cases, demonstrated an overall perioperative rate of stroke of 7.9%, perioperative death of 3.4%, and perioperative stroke or death of 9.5%.
- Advanced age and coma reduce favourable outcomes of surgical management of intracerebral hemorrhage and need to be considered.

See the "Contraindications" field for situations where careful consideration of the balance of the potential risks and benefits of recombinant tissue plasminogen activator (rt-PA) therapy must be given.

## CONTRAINDICATIONS

### CONTRAINDICATIONS

Absolute contraindications to recombinant tissue plasminogen activator (rt-PA) therapy:

- Uncertainty about time of stroke onset (e.g., patients awaking from sleep)
- Coma or severe obtundation with fixed eye deviation and complete hemiplegia
- Only minor stroke deficit which is rapidly improving
- Seizure observed or known to have occurred at onset of stroke
- Hypertension: systolic blood pressure  $\geq 185$  mmHg; or diastolic blood pressure  $> 110$  mmHg on repeated measures prior to study
- Clinical presentation suggestive of subarachnoid haemorrhage even if the computed tomography scan is normal
- Presumed septic embolus
- Patient having received heparin within the last 48 hours and has elevated partial thromboplastin time (PTT) or has a known hereditary or acquired

- haemorrhagic diathesis (e.g., prothrombin time (PT) or activated PTT (APTT) greater than normal)
- International normalized ratio (INR) >1.5
- Platelet count is <100,000 uL
- Serum glucose is <2.8 mmol/L or >22.0 mmol/L

Relative\* contraindications to rt-PA therapy:

- Severe neurological impairment with National Institutes of Health (NIH) Stroke Scale score >22
- Age >80 years
- Computed tomography (CT) evidence of extensive middle cerebral artery (MCA) territory infarction (sulcal effacement or blurring of gray-white junction in greater than 1/3 of MCA territory)
- Stroke or serious head trauma within the past 3 months where the risks of bleeding are considered to outweigh the benefits of therapy
- Major surgery within the last 14 days
- Patient has known history of intracranial haemorrhage, subarachnoid haemorrhage, known intracranial arteriovenous malformation or previously known intracranial neoplasm that, in the opinion of the clinician, the increased risk of intracranial bleeding would outweigh the potential benefits of treatment
- Suspected recent (within 30 days) myocardial infarction
- Recent (within 30 days) biopsy of a parenchymal organ or surgery that, in the opinion of the responsible clinician, would increase the risk of unmanageable (e.g., uncontrolled by local pressure) bleeding
- Recent (within 30 days) trauma with internal injuries or ulcerative wounds
- Gastrointestinal or urinary tract haemorrhage within the last 30 days or any active or recent haemorrhage that, in the opinion of the responsible clinician, would increase the risk of unmanageable (e.g., by local pressure) bleeding
- Arterial puncture at noncompressible site within the last 7 days
- Concomitant serious, advanced or terminal illness or any other condition that, in the opinion of the responsible clinician would pose a risk to treatment

\*Use tPA with caution. In each situation careful consideration of the balance of the potential risks and benefits must be given.

## QUALIFYING STATEMENTS

### QUALIFYING STATEMENTS

- This document is a general guide to appropriate practice, to be followed subject to the clinician's judgement and the patient's preference in each individual case. The guidelines are designed to provide information to assist decision-making and are based on the best evidence available at the time of development.
- The guidelines should not be seen as an inflexible recipe for stroke care; rather, they provide a framework that is based on the best available evidence that can be adapted to local needs, resources and individual circumstances.



## IMPLEMENTATION OF THE GUIDELINE

### DESCRIPTION OF IMPLEMENTATION STRATEGY

Reviewing the evidence and developing evidence-based recommendations for care involves only the first steps to ensuring that evidence-based care is available. Following publication of the Clinical Guidelines for Acute Stroke Management, the guidelines must be disseminated to all those who provide care of relevance to acute stroke care, who may then identify ways in which the guidelines may be taken up at a local level.

Strategies by which guidelines may be disseminated and implemented include:

- Distribution of education materials - for example: mailing of guidelines to stroke clinicians via existing stroke networks will be undertaken. Concise guidelines (in particular for General Practitioners [GPs]) are also planned with GP networks utilised to circulate this new information. Guidelines documents will also be sent to all appropriate universities, colleges, associations, societies and other professional organisations.
- Educational meetings - for example: interdisciplinary conferences or internet based 'web conferences' are planned. Resources will be developed to aid workshop facilitators identify barriers and solutions in the implementation phase.
- Educational outreach visits - A peer support model using sites viewed as 'champions' in aspects of acute stroke management may be used in collaboration with national audit results.
- Local opinion leaders - Educational resources will utilise key opinion leaders. It is also planned to have local champions facilitate workshops in their local areas.
- Audit and feedback - Data from the first national audit of acute stroke will be fundamental to the implementation of these guidelines. A copy of relevant indicators covering organisation of care and clinical care will be available from the National Stroke Foundation (NSF) along with key reports.
- Reminders - Electronic reminders will be used once local teams have identified key areas of improvement and commenced planned strategies.

A systematic review of the above dissemination and implementation strategies found that there was difficulty in interpreting the evidence of the effectiveness of these interventions due to methodological weaknesses, poor reporting of the study setting and uncertainty about the generalisability of the results. However, most of the strategies appear to have modest effectiveness in implementing evidence based care, but it is unclear if single interventions are any better or worse than multiple interventions. Thus, all of the above strategies may be used where appropriate for implementation of the Clinical Guidelines for Acute Stroke Management. Specific strategies will also be considered when targeting general practice in line with the Royal Australian College of General Practitioners (RACGP) Guidelines for "Putting prevention into practice". Implementation of these stroke Guidelines may also be supported by existing resources and networks. These include:

- The Stroke Services in Australia report, which outlines how stroke services may be organised in different parts of Australia and the resources that may be needed to do this (available at [www.strokefoundation.com.au](http://www.strokefoundation.com.au)).
- The Stroke Care Pathway, which provides a checklist addressing key processes of care as outlined in both documents (Acute, and Rehabilitation and Recovery) and a guide to developing local protocols (available from [www.strokefoundation.com.au](http://www.strokefoundation.com.au) or [www.health.gov.au](http://www.health.gov.au)).
- Other specific workshop resources to aid implementation (e.g., CD Rom or self directed workbook).
- Various networks including Stroke Services New South Wales (NSW), Queensland (QLD) Stroke collaborative and other state and local networks.

In considering implementation of these Guidelines at a local level, health professionals are encouraged to identify the barriers and facilitators to evidence-based care within their environment to determine the best strategy for local needs.

### **Consumer Versions of the Clinical Guidelines**

Consumer versions of the Clinical Guidelines for Acute Stroke Management and Clinical Guidelines for Stroke Rehabilitation and Recovery documents have been developed through partnerships between the National Stroke Foundation and State Stroke Associations throughout Australia. Given the different needs of stroke survivors and their families at different stages of recovery, the two Clinical Guideline documents are presented as three books for consumers. These books are available through the National Stroke Foundation and State Stroke Associations.

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

## **IMPLEMENTATION TOOLS**

### **Patient Resources**

For information about [availability](#), see the "Availability of Companion Documents" and "Patient Resources" fields below.

## **INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES**

### **IOM CARE NEED**

Getting Better  
Staying Healthy

### **IOM DOMAIN**

Effectiveness  
Patient-centeredness

Safety  
Timeliness

## IDENTIFYING INFORMATION AND AVAILABILITY

### BIBLIOGRAPHIC SOURCE(S)

Acute medical and surgical management. In: National Stroke Foundation. Clinical guidelines for acute stroke management. Melbourne (Australia): National Stroke Foundation; 2007 Oct. p. 22-9.

### ADAPTATION

Not applicable: The guideline was not adapted from another source.

### DATE RELEASED

2007 Oct

### GUIDELINE DEVELOPER(S)

National Stroke Foundation (Australia) - Private Nonprofit Organization

### SOURCE(S) OF FUNDING

Australian Government Department of Health and Ageing

### GUIDELINE COMMITTEE

Expert Working Group

### COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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## **FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST**

All members of the working group completed and signed a declaration of potential conflicts of interest with development of these guidelines. Most had no perceived conflicts. The reasons provided for potential conflicts primarily involved receiving money from non commercial and commercial organisations specifically for undertaking clinical research. This was expected given the expertise of members of the working group in clinical research. Only a small number of members had received financial support from commercial companies for providing consultancy or lecturing.

## **ENDORSER(S)**

Australian and New Zealand Society for Geriatric Medicine - Medical Specialty Society  
Australian College of Rural and Remote Medicine - Professional Association  
Australian Physiotherapy Association - Medical Specialty Society  
BeyondBlue: The National Depression Initiative - National Government Agency [Non-U.S.]  
Council of Ambulance Authorities (Australia) - Professional Association  
Dietitians Association of Australia - Professional Association  
Occupational Therapy Australia - Professional Association  
Royal Australian and New Zealand College of Radiologists - Professional Association  
Speech Pathology Australia - Medical Specialty Society  
Stroke Society of Australasia - Disease Specific Society

## **GUIDELINE STATUS**

This is the current release of the guideline.

## **GUIDELINE AVAILABILITY**

Electronic copies: Available in Portable Document Format (PDF) from the [National Stroke Foundation \(Australia\) Web site](#).

Print copies: Available from the National Stroke Foundation (Australia), Level 7, 461 Bourke Street, Melbourne Victoria 3000, Australia.

## **AVAILABILITY OF COMPANION DOCUMENTS**

The following is available:

- Clinical guidelines for acute stroke management – supplement. Melbourne (Australia): National Stroke Foundation; 2007 Oct. 67 p. Electronic copies: Available in Portable Document Format (PDF) from the [National Stroke Foundation \(Australia\) Web site](#).

## **PATIENT RESOURCES**

The following are available:

- Early testing and treatment. Melbourne (Australia): National Stroke Foundation; 2005. 16 p.
- Stroke rehabilitation. Melbourne (Australia): National Stroke Foundation; 2005. 19 p.
- Long term recovery. Melbourne (Australia): National Stroke Foundation; 2005. 16 p.

Electronic copies: Available in Portable Document Format (PDF) from the [National Stroke Foundation \(Australia\) Web site](#).

Print copies: Available from the National Stroke Foundation (Australia), Level 7, 461 Bourke Street, Melbourne Victoria 3000, Australia.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

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